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09/754,010	01/03/2001	Mark E. Dillon	E-1950	3438
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PURDY, KYLE A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/754,010

Applicant(s)

DILLON, MARK E.

Examiner

Kyle Purdy

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-54 is/are pending in the application.
- 4a) Of the above claim(s) 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 08/21/2008 wherein claims 34 and 41 have been amended.
2. Claims 34-45 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 08/21/2008 regarding the rejection of claims 34-36 made by the Examiner under 35 USC 102(c) over Lindqvist et al. (US 6051747) have been fully considered but they are not found persuasive.

4. In regards to the 102(c) rejection, Applicant asserts the following:

A₁) The invention as claimed is structurally distinguishable from the prior art since the foam layer of the reference is not arranged to contact a wound.

5. With respect to assertion A, the Examiner respectfully disagrees. The instant invention is directed to a product and not a method of using the product, i.e. contacting a wound when the contacting side is the side facing the wound (rephrased, see amendment). Determination of patentability is based on the product itself. The current amendment is an intended use for how the product is to be used. However, this does not materially affect the product itself. The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. The examiner points out that the prior art discloses a foam layer that is not occluded by the gel and 2) a polyurethane foam layer in Figure 2. It is noted that the gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the

wound. See column 2, lines 50-53. Thus, the foam does have a wound-contacting surface since the gel layer or adhesive layer does not cover the entire surface of the foam layer. Therefore, Lindqvist's structure and the instant invention as claimed are not structurally distinguishable and the prior art's wound dressing is capable of performing the recited intended use. Meaning the wound dressing is capable of being used upside down. Again the examiner points out that the claimed intended use of the dressing does not impart a structural difference since the prior art may also be turned upside down since it has a foam layer and a membrane layer.

6. Applicants arguments filed 08/21/2008 regarding the rejection of claims 34, 36, 40 and 45 made by the Examiner under 35 USC 102(b) over Hofeditz et al. (US 4552138) have been fully considered but they are not found persuasive.

7. In regards to the 102(b) rejection, Applicant asserts the following:

A₂) The invention as claimed is structurally distinguishable from the prior art since the foam layer of the reference is not arranged to contact a wound; and

B₂) the covering layer is not disclosed to be the foam layer but rather a layer that covers the surface of the gel.

8. With respect to assertion A₂, the Examiner respectfully disagrees. First, the instant invention is directed to a product and not a method of using the product, i.e. contacting a wound when the contacting side is the side facing the wound (rephrased, see amendment). The instant invention is directed to a wound dressing comprising 1) a membrane layer and 2) a foam layer. Hofeditz discloses a 1) a gel layer that reads on the membrane layer since a membrane is defined as a "thin, soft pliable sheet or layer" and 2) a polyurethane foam layer. See Examples 5 and 6.

The membrane layer and the foam layer are both capable of contacting a wound surface. The current amendment is an intended use for how the product is to be used. However, this does not materially affect the product. The teaching of Hofeditz still anticipates the instant claims.

9. With respect to assertion B₂, Applicant is directed to Examples 5 and 6. The Examples clearly disclose a membrane layer being laminated 'with an open-pore foam of polyurethane'. Thus, the resultant structure being 1) a membrane and 2) a foam layer. Applicants arguments are not found persuasive.

10. Applicants arguments filed 08/21/2008 regarding the rejection of claims 34-36, 38, 42, 43 and 45 made by the Examiner under 35 USC 102(b) over Freeman (US 5681579) have been fully considered but they are not found persuasive.

11. In regards to the 102(b) rejection, Applicant asserts the following:

A₃) The invention as claimed is structurally distinguishable from the prior art since the foam layer of the reference is not arranged to contact a wound.

12. With respect to assertion A₃, the Examiner respectfully disagrees. The instant invention is directed to a product and not a method of using the product, i.e. contacting a wound when the contacting side is the side facing the wound (rephrased, see amendment). The instant invention is directed to a wound dressing comprising 1) a membrane layer; 2) an adhesive layer; and 3) a foam layer. Hofeditz discloses a 1) a gel layer that reads on the membrane layer since a membrane is defined as a "thin, soft pliable sheet or layer"; 2) an adhesive; and 3) a polyurethane foam layer. See Figures. The foam and the membrane layer are both capable of contacting a wound surface. The current amendment is an intended use for how the product is to be used and

does not materially affect the product. The teaching of Freeman still anticipates the instant claims.

13. Applicants arguments filed 08/21/2008 regarding the rejection of claims 37, 39-42 made by the Examiner under 35 USC 103(a) over Lindqvist et al in view of Lorenz et al (US 5258421), evidenced by US 4832009 have been fully considered but they are not found persuasive.

14. In regards to the 103(a) rejection, Applicant asserts the following:

A₄) None of the cited references teach using a pigment to provide a visual indicator for differentiating one side of the dressing from the other; and

B₄) it would not have been obvious to one of ordinary skill to use IPN.

15. With respect to assertion A₄, the Examiner respectfully submits that the use of a pigment to provide a visual indication for differentiating one side from the other is an intended use of the pigment. While the inclusion of the pigment imparts a structural limitation, the intended use does not. Lorenz teaches the structure can contain pigments and dyes. Regardless of what function these dyes/pigments serve, the fact remains the same that it would have been obvious to one of ordinary skill in the art to include dye and pigments in any one of the layers espoused by Lorenz, including that of the adhesive layer.

16. With respect to assertion B₄, the premise of the rejection is Lorenz provides the motivation to substitute Lindqvist's polyurethane film with the instant IPN film by teaching both as functionally equivalent. Applicant has not provided any arguments or evidence of the unobvious difference.

17. Applicants arguments filed 08/21/2008 regarding the rejection of claim 44 made by the Examiner under 35 USC 103(a) over Lindqvist et al and Freeman have been fully considered but they are not found persuasive.

18. In regards to the 103(a) rejection, Applicant asserts the following:

A₅) It would not have been obvious to arrive at an invention where the membrane layer is 50 microns thick.

19. With respect to assertion A₅, the Examiner respectfully disagrees. As noted in the office action, Lindqvist teaches the foam layer as having a thickness of 1000 microns to 10,000 microns and the polyurethane layer as having a thickness of 25 microns. However, Freeman cures this deficiency as teaching a membrane layer having a thickness between 35 and 76 microns. Therefore, one of ordinary skill would readily be ca[able of combining the two teachings with a reasonable expectation for arriving at product having the instantly claimed properties.

Maintained Rejections
Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

21. Claims 34-36 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindqvist et al (6,051,747).

22. Lindqvist et al disclose a wound dressing a gel layer (3), which is reticulated into a polyurethane foam layer (2) with open cells (fenestrations) and a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer made of a polyurethane film (5). See Figures. The gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound, excess wound fluid can be drawn into the foam material 2 and absorbed thereby. The polyurethane film is glued to the foam layer. See column 5, lines 63-65. The polyurethane film has high vapor permeability and a thickness of 0.025 mm (25 microns). See column 5, lines 63-65. Note that the polyurethane film in this embodiment read on the instant membrane layer since “membrane” is defined as “a thin sheet of natural or synthetic material”. Note also in this embodiment the glue reads on the adhesive layer since the glue acts to bond the foam and the film.

23. With regard to lines 4-9 of independent claim 34, it is the examiner’s position that since Lindqvist discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofeditz et al (4,552,138).

26. Hofeditz et al disclose a dressing material comprising at least one layer of hydrophilic, transparent polymeric gel (see column 2, lines 44-45) and a carrier material. Example 5 discloses the gel layer laminated to an open-pore (fenestrations) polyurethane foam. Hofeditz discloses the additional use of dyes and pigments. See claim 13 and examples.

27. It should be noted that membrane is defined as a “thin, soft pliable sheet or layer”; thus Hofeditz polymeric gel layer reads on “membrane layer”.

28. With regard to lines 4-9 of independent claim 34, it is the examiner’s position that since Hofeditz discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the wound dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use.

29. Claims 34-36, 38, 42-43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5,681,579).

30. Freeman discloses a polymeric support wound dressing. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) bonded by adhesives (13) means to a hydrocolloid containing polymeric layer (12) (first layer).



The occlusive layer 11 has an upper or outer surface 14, which is open to the atmosphere and an inner surface 13, which is the side toward the skin. The occlusive layer is preferably a polyurethane foam. See column 4, lines 30-31. The adhesive layer may for example extend across the entire under surface 13 of the occlusive layer or only a portion of it. The polymeric support layer 12 is any polymeric material useful in medical settings and is in the form of a web, net, perforated film or perforated layer. The polymeric support layer 12 contains a hydrocolloid either blended with the polymeric material. When the hydrocolloid is blended with the polymeric material it is preferred that the two materials be extruded together to form a film. See column 5, lines 1-30. It should be noted that a membrane is defined as a "thin, soft pliable sheet or layer"; thus Freeman's polymeric support reads on instantly claimed "membrane layer". The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8. The adhesive layer is made of various substances including silicone rubber. See column 6, line 31.

31. Dressing A discloses a hydrocolloid centered on polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45.

32. With regard to lines 4-9 of independent claim 34, it is the examiner's position that since the prior art discloses a wound dressing that is multi-layered wherein the two layers are different, i.e. made of different material; thus the would dressing is capable of meeting the intended use recited in lines 4-9. The examiner points out that the instant invention and the prior art are not structurally distinguishable and thus the prior art is capable of performing the recited intended use. Moreover, a portion of layer 11, the foam, along with layer 12, contacts the skin surface as disclosed by Freeman on column 4, lines 13-15.

Claim Rejections - 35 USC § 103

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

34. Claims 37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.

35. The disclosure of Lindqvist has been set forth above.

36. Lindqvist does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer. Further, the addition of a pigment is not taught.

37. Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate. The backing substrate provides liquid barrier properties and may be a polymer film such as polyurethane film or silicone-polytetrafluoroethylene IPN membrane film. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

38. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al and Lorenz et al and replace Lindqvist's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and

the instant film have Liquid barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in Lindqvist's wound dressing over Lindqvist's polyurethane film for the advantages taught by Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site. A skilled artisan would have reasonably expected success and similar results since Lorenz teaches both Lindqvist's polyurethane film and instant silicone-polytetrafluoroethylene IPN function in a similar manner, i.e. functional equivalents (both are liquid impervious layers that are utilized in wound dressing).

39. With regard to claim 40, it would have been obvious to add a pigment to Lindqvist's gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

40. With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

41. With regard to claim 42, pores (fenestrations) are a property of silicone-polytetrafluoroethylene IPN films. US '009 substantiates this. Note column 1, lines 45-60 of US '009.

42. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) by itself or in view of Freeman (5,681,579).

43. The disclosure of Lindqvist has been set forth above. The reference teaches the foam has a thickness of 1-10mm (1000microns to 10,000 microns), and a liquid impervious layer (polyurethane film) has a thickness of 0.025 mm (25 microns).

44. Lindqvist does not teach the instant thickness of the membrane layer, i.e. 50 microns.

45. Freeman teaches a polymeric support wound dressing, which comprises a occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesives (adhesive layer) means to a perforated film (12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid centered on a polyurethane foam, which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45. The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8.

46. It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Lindqvist and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam

layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

47. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist and Freeman and manipulate the thickness of the liquid impervious layer from 25 microns to 50 microns. One would have been motivated to do so since Freeman teaches polyurethane films may be in a thickness of 35-76 microns. Therefore, a skilled artisan would have been motivated to manipulate the thickness of this layer since the polymeric layer functions to support the foam layer. Thus, depending on factors such as the weight and thickness of the foam layer one would have been motivated to utilize the appropriate thickness to support the foam layer and provide strength to the entire structure.

48. Claims 37, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al (5,258,421) and as evidenced by US 4832009.

49. The disclosure of Freeman has been set forth above.

50. Freeman does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer or a pigment.

51. Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film

such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55. It should be noted that IPN is implicitly translucent.

52. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Freeman et al and Lorenz et al and replace Freeman's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have Liquid barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in the wound dressing over Freeman's polyurethane film for the advantages taught by Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

53. With regard to claim 40, it would have been obvious to add a pigment to the gel if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly

claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

54. With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

Conclusion

55. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

56. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

57. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/

Examiner, Art Unit 1611

October 28, 2008

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611